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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,624	02/14/2002	Wenyuan Shi	02307K-186430US	2797

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/077,624	SHI ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *2-20,25,26,28 and 30-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,21-24,27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9-18-2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's argument that claims 24 and 26 should be examined has been fully considered. Given that *Pseudomonas spp.* can be a cariogenic organism claim 24 is hereby rejoined. However, given that claim 26 depends on claim 25 which is specifically drawn to a non-elected organism, the withdrawal of claim 26 is deemed proper and is maintained.

The amendment filed on 12-11-2006 is acknowledged. Claims 16, 18, 20 and 22 have been amended. Claims 1-48 are pending. Claims 2-20, 25-26, 28 and 30-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1, 21-24, 27 and 29 are currently under examination.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has still not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/910,358, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the prior filed application does not disclose the use of Novispirin G10 or SEQ ID NO:17 of the instant application. Consequently, the filing date of the instant application (2-14-2002) will be used for prior art purposes.

Information Disclosure Statement

The Information Disclosure Statements filed on 9-18-2007 has been considered. An initialed copy is attached hereto.

Claim Objections Maintained

Claims 1, 21-24, 27 and 29 are objected to as being drawn, in part, to non-elected inventions for the reasons set forth in the objection to claims 1, 21-23, 27 and 29. Appropriate correction is required.

Claim Rejections Withdrawn

The rejection of claims 23, 27 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections Maintained

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The provisional rejection of claims 1, 23, 27 and 29 under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 21, 24 and 26 of copending Application No. 10/706,391 is maintained for reasons of record. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant's traversal citing the double patenting issue is not ripe for consideration is noted.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provision rejection of claim 21 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 20 of copending Application No. 10/706,391 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to compositions comprising a targeting moiety and an anti-microbial peptide moiety wherein said anti-microbial peptide moiety is Novispirin 10 and the target microbial organism is a *Pseudomonas* species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's traversal citing the double patenting issue is not ripe for consideration is noted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 21-24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehrer et al. (U.S. Patent 6,492,328) in view of Goldenberg (U.S. Patent 5,332,567) for the reasons set forth in the previous Office action in the rejection of claims 1, 21-23, 27 and 29.

Applicant argues:

1. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

2. Lehrer et al. does not contemplate coupling Novispirin to a targeting moiety.

3. The immunoconjugates contemplated in Goldenberg are antibodies/fragments chemically linked to a drug, toxin or detecting agent. Said linkages are non-specific which create the very problems the instant invention was designed to overcome.

4. The skilled artisan would not have attempted a conjugation of a targeting moiety to Novispirin based on the cited references nor would they have had any reasonable expectation of success.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, that KSR decision forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obvious. See the recent

Board decision *Ex parte Smith,--USPQ2d--,* slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396). In this instance all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

With regard to Points 2 and 3, the claims do not contain limitations with regard to the type of "linkage".

With regard to Point 4, it would have been obvious for one of ordinary skill in the art to use the antibody conjugate system disclosed by Goldenberg as the delivery vehicle for the Novispirin G10 disclosed by Lehrer et al. in treating a *Pseudomonas* infection in order to take advantage of the increased target site delivery efficiency associated with Goldenberg's conjugates. Moreover, one would have a reasonable expectation of success since Goldenberg discloses a multitude of antimicrobial agents can be used in his conjugates.

The instant claims are drawn to compositions comprising a targeting moiety and an anti-microbial peptide moiety wherein the targeting moiety is coupled to the anti-microbial; the targeting moiety is specific for a *Pseudomonas* species; and the anti-microbial peptide moiety is Novispirin G10 (optionally with the sequence of SEQ ID NO:17).

Lehrer et al. disclose the use of Novispirin G10 to treat bacterial infections, fungal infections and protozoan infections (see column 6, lines 16-39). Lehrer et al. further disclose Novispirins, generally, and Novispirin G10 specifically, are particularly useful for killing *Pseudomonas aeruginosa* (see column 5, lines 55-57 and Figure 2).

Lehrer et al. differs from the instant invention in that they don't explicitly disclose the use of Novispirin G10 coupled to a targeting moiety.

Goldenberg discloses the use of immunoconjugates to treat microbial infections wherein said immunoconjugate comprises an antibody or antibody fragment coupled to a therapeutic agent (see column 2, lines 37-57). Goldenberg further discloses that antimicrobial agents can be used to treatment of bacterial infections (see column 3, lines 7-17) and that the term "microbe" encompasses bacteria (see column 3, line 24). Finally, Goldenberg discloses the use of antibody conjugates allows the localization of the therapeutic agent at the target site (i.e. the site of infection) with a higher efficiency and an enhanced target to non-target ratio (see column 3, lines 55-58). This would reduce the amount of antimicrobial agent required to treat a given infection and thereby reducing any toxicity associated with said agent.

It would have been obvious for one of ordinary skill in the art to use the antibody conjugate system disclosed by Goldenberg as the delivery vehicle for the Novispirin G10 disclosed by Lehrer et al. in treating a *Pseudomonas* infection in order to take advantage of the increased target site delivery efficiency associated with Goldenberg's conjugates.

One would have a reasonable expectation of success since Goldenberg discloses a multitude of antimicrobial agents can be used in his conjugates (including drugs).

Claims 1, 21-24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehrer et al. (U.S. Patent 6,492,328) in view of Shi et al. (U.S. Patent Application Publication US 2004/0052814A1) for the reasons set forth in the previous Office action in the rejection of claims 1, 21-23, 27 and 29.

Applicant argues:

1. Shi et al. and the present application were subject to an obligation of assignment to the same organization and hence is disqualified as prior art under 35 U.S.C. 103.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, Applicant's statements are insufficient to overcome the instant rejection. Evidence of common obligation of assignment must be provided in order to disqualify a copending application under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are drawn to compositions comprising a targeting moiety and an anti-microbial peptide moiety wherein the targeting moiety is coupled to the anti-microbial; the targeting moiety is specific for a *Pseudomonas* species; and the anti-microbial peptide moiety is Novispirin G10 (optionally with the sequence of SEQ ID NO:17).

As outlined previously, Lehrer et al. disclose the use of Novispirin G10 to treat bacterial infections, fungal infections and protozoan infections (see column 6, lines 16-39). Lehrer et al. further disclose Novispirins, generally, and Novispirin G10 specifically, are particularly useful for killing *Pseudomonas aeruginosa* (see column 5, lines 55-57 and Figure 2).

Lehrer et al. differs from the instant invention in that they don't explicitly disclose the use of Novispirin G10 coupled to a targeting moiety.

Shi et al. disclose the use of a fusion protein comprising a recognition sequence and an antimicrobial peptide to treat bacterial infections (see paragraph [0002]). Shi et al. further disclose that a multitude of different peptides can be used (see paragraph [0023]. Finally, Shi et

al. disclose that their fusion proteins offer the advantage of targeted delivery of antimicrobial peptides that allows for a lower concentration of antimicrobial peptide to be administered thereby substantially reducing any side effects associated with the antimicrobial peptide (see paragraph [0030]).

It would have been obvious for one of ordinary skill in the art to use the fusion protein disclosed by Shi et al. the delivery vehicle for the Novispirin G10 disclosed by Lehrer et al. in treating a *Pseudomonas* infection in order to take advantage of the increased target site delivery efficiency associated with Shi's fusion proteins.

One would have a reasonable expectation of success since Shi et al. disclose a multitude of antimicrobial peptides can be used in their fusion proteins.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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/Robert A. Zeman/
Primary Examiner, Art Unit 1645
September 2, 2008